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The Agency disagrees with the premise that only examples supported by binding regulation or judicial precedent would be valid evidence of Agency interpretation. FDA cited the examples to illustrate that the Agency has over the years consistently taken the position that express drug or device claims are not required for a finding of intended pharmacological use or effect. These examples constitute highly relevant evidence of the Agency's past interpretations of its governing statute.

Further, FDA's statements in *Federal Register* preambles and proposed regulations—although not binding—are official statements of Agency position. *See* 21 CFR 10.85(d)(1) and (e) (texts of proposed and final regulations, and related preambles, are valid FDA interpretations). Although the Agency did not concur fully with its advisory committee in the vaginal products example, the position expressed in the example was that of the Agency. *See* 59 FR 5226, 5227 (Feb. 3, 1994). These and other official Agency interpretive statements deserve strong consideration. Notifications to manufacturers also represent official Agency positions. *See* 21 CFR 10.85(d)(1); *see also Kickapoo Oil Co. v. Murphy Oil Corp.*, 779 F.2d 61, 66 (Temp. Em. Ct. App. 1985) ("Notice of Probable Violation" constitutes agency interpretation).

The examples document the Agency's consistent historical position that intended use is not limited to express claims. *See Udall v. Tallman*, 380 U.S. 1, 17-18 (1965) (consistent past agency practice can be evidence of agency interpretation). The examples cover a number of years and represent a variety of circumstances. They cover both individual products and categories of products. They include drugs and devices. The intended users ranged from physicians and researchers to ordinary consumers to those seeking a cocaine substitute. They include intended use based on both product effect and

consumer use. The Agency's application of the intended use concept is not a new regulatory construct. Rather, as these examples illustrate, the Agency has applied the concept in a variety of contexts, both formal and informal. Whether any of these examples represent "binding" interpretation is irrelevant given the limited purpose for which they are cited. As the court in *Kickapoo Oil* found, enforcement actions, notices of potential violations, statements in various briefs, and similar documents all constitute persuasive evidence of an agency's past interpretation of its governing statute.

4. One comment attempts to distinguish tobacco products from khat by arguing that FDA relied on product effect and consumer use to regulate khat only because there were no express claims, whereas tobacco products have express claims (e.g., for smoking taste and pleasure). The Agency disagrees. Even if the khat had been labeled as a decorative plant or a culinary herb, for example, such express claims would not have been binding and FDA would have taken the same action. (In fact, as the comment acknowledges, FDA suspected that the khat might have been falsely declared as a permitted Egyptian vegetable.)

The same comment also argues that FDA was merely aiding a sister agency, the Drug Enforcement Agency (DEA), in controlling a product that DEA considered to be a drug of abuse. The comment notes that it is not necessary to establish intended use for a DEA-controlled substance. In fact, for a decade after FDA first issued the khat Import Alert, DEA did not have jurisdiction over the product. Even after the active ingredient was listed as a controlled substance, FDA retained separate jurisdiction to detain the product. Obviously, any FDA detention action—before or after khat was scheduled as a controlled substance—had to be accomplished under FDA's authority.

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The comment further argues that the example is not relevant because the evidentiary standard for import detention is low (i.e., that the product only has to "appear" to be violative under section 801(a) of the Act, 21 U.S.C. 381). A differing evidentiary standard does not render the evidence relied upon by the Agency in determining khat's intended use irrelevant to establishing intended use. In determining whether an imported product "appears" to be a drug or device, the Agency uses the same kinds of evidence as it does in determining whether a domestic product "is" a drug or device. While the Agency's evidentiary burden under section 801(a) may be lower than it is when the Agency finally determines that a product is a drug or device under the Act, the types of evidence that are relevant do not differ.

Still another comment asserts that, because khat is intended to be used as a tea, it is a food and not a drug. The Agency agrees that the Federal Food, Drug, and Cosmetic Act excludes a food from the definition of "drug" under section 201(g)(1)(C). However, khat is not a food because it is not used primarily for taste, aroma, or nutritive value. *Nutrilab, Inc.*, 713 F.2d at 337. Instead, its foreseeable use was to obtain stimulant narcotic effects. Moreover, the Agency notes that khat is not used exclusively as tea, but is also chewed and smoked like tobacco.

F. RESPONSE TO ADDITIONAL COMMENTS

In this section, the Agency responds to additional comments regarding the evidence that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body" and the Agency's use of that evidence.

1. Some comments assert that FDA may not rely on evidence relating to particular manufacturers to find intended use for all manufacturers of a particular product, but must instead determine intended use on a product-by-product basis by producing evidence specific to each individual manufacturer and even to each individual brand of tobacco products. The Agency disagrees with these comments. In appropriate circumstances, FDA can determine that a type of product is subject to its jurisdiction without focusing on the individual manufacturer or brand.

As discussed in other parts of section II., the evidence of intended use applies to all cigarettes and smokeless tobacco products on the market. This evidence establishes that cigarettes and smokeless tobacco are highly addictive, cause other psychoactive effects (such as relaxation and stimulation), and affect weight regulation and that these effects are widely accepted in the scientific community. Based on this evidence, it is foreseeable to any reasonable manufacturer that cigarettes and smokeless tobacco will have and be used for these addictive, psychoactive, and other pharmacological effects. The evidence also shows that *actual* consumer use of these products for their pharmacological effects is predominant and, in fact, nearly exclusive. Given the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco and the actual consumer use of cigarettes and smokeless tobacco for pharmacological effects, the Agency concludes that all of these products are "intended to affect the structure or any function of the body."

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In addition, the Agency has collected evidence of the tobacco industry's statements, actions, and research demonstrating the industry's widespread awareness of the addictive and other pharmacological effects of cigarettes and smokeless tobacco, the industry's widespread knowledge that consumers use its products for these effects, and the industry's widespread manipulation of nicotine levels in its products to ensure that adequate amounts of nicotine are delivered to consumers. This evidence is further objective evidence that these products are "intended to affect the structure or any function of the body."

In the case of cigarettes, the evidence shows that the major manufacturers engaged in extensive research into nicotine pharmacology either as individual companies or through the industry-funded Council for Tobacco Research. Moreover, the evidence shows that the major cigarette manufacturers manipulate the nicotine level in cigarettes through techniques such as blending, the use of ammonia technologies, and the design of cigarette filters and ventilation. In the case of smokeless tobacco, the evidence shows that the major manufacturers of smokeless tobacco have also sponsored research into nicotine pharmacology either as individual companies or through the industry-funded Smokeless Tobacco Research Council. In addition, the evidence shows widespread nicotine manipulation by major smokeless tobacco manufacturers through pH adjustments or the use of teabag-like pouches that reduce nicotine delivery in their starter products.

Although the Agency often chooses to take enforcement actions against particular manufacturers of a specific product rather than to assert regulatory authority over all manufacturers of the product as a group, the Agency may choose a different regulatory approach when circumstances warrant. The Agency has concluded that such a different

approach is appropriate here. In concluding that these products are drug delivery devices within the meaning of the Act, the Agency is relying not on product labeling or express representations in promotional materials,[1138] but on other relevant objective evidence of intended use—dispositive evidence concerning the foreseeable pharmacological effects and uses of these products, actual consumer use of these products, and evidence of industry-wide actions, practices, and knowledge. Further, the public health concerns that the Final Rule seeks to address—the appeal and availability of tobacco products to young people—can be addressed effectively and efficiently only through the regulation of all cigarettes and smokeless tobacco as a group.

There is ample precedent to support FDA regulation of essentially identical products as a group, rather than setting criteria or restrictions on a product-by-product or manufacturer-by-manufacturer basis. For example, in administering the Act's device provisions, the Agency traditionally classifies at one time all products that are sufficiently similar that they can be considered the same type of device for purposes of applying the Act's regulatory controls. *See* 21 CFR 860.3(i) (definition of "generic type of device"). In making these device classification decisions, the Agency relies on the cumulative evidence from several manufacturers. Further, reclassification of one product of a particular type results in the reclassification of the entire group. *See* Proposed Rule: Medical Devices Classification Procedures, 42 FR 46028 (Sep. 13, 1977); *see also* Final Rule: Medical Devices Classification Procedures, 43 FR 32988 (Jul. 28, 1978). Thus, FDA applies the same regulatory requirements to all devices within an identified device

[1138] As discussed in section II.E.2., above, however, the implied claims in tobacco manufacturers' promotional materials provide further support for the Agency's conclusion.

type. This approach is necessary to provide similar regulatory treatment for essentially identical products of different manufacturers and distributors. *See* 42 FR 46031; 43 FR 32989. Proceeding otherwise would require FDA to classify individually each manufacturer's device and to undertake the classification process whenever a new manufacturer marketed a product within an existing category of devices. Because cigarettes and smokeless tobacco affect the structure and function of the body and are devices under the Act, it is consistent with the Agency's approach to device classification to determine the intended use of all cigarettes and smokeless tobacco.

Similarly, the Agency limits the use of certain potentially dangerous ingredients in drug products by establishing uniform standards rather than manufacturer-specific restrictions. *See, e.g.*, 21 CFR 310.506 (1974 action restricting use of vinyl chloride); 21 CFR 310.507 (1977 action restricting use of trichloroethane in aerosol products); 21 CFR 310.508 (1975 action restricting use of halogenated salicylanilides); 21 CFR 310.513 (1976 action restricting use of chloroform in drug products).

Regulating the products of some cigarette and smokeless tobacco manufacturers while allowing others to be marketed without the restrictions that FDA has determined are necessary would frustrate important public health goals. For example, the goal of reducing tobacco use among young people would be severely compromised if one tobacco company could continue advertising in the manner limited by the regulations. Similarly, it would be anomalous to prohibit some manufacturers, but not others, from filling vending machines with cigarettes in facilities accessible to persons under the age of 18. Furthermore, if FDA proceeded against some but not all manufacturers, the result would be inequitable because some companies would be subject to FDA regulation while their

competitors remain unregulated. The Supreme Court has recognized that proceeding against similar products one at a time can result in "great inequities . . . . [because] competitors selling drugs in the same category would go scot-free until the tedious and laborious procedures of litigation reached them." *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 626 (1973).

One comment cites a statement in *Action on Smoking and Health v. Harris (ASH)*, 655 F.2d 236, 242 n.10 (D.C. Cir. 1980), that "[t]he very structure of the Act . . . calls for case-by-case analysis," and argues that the statement supports its argument that the Agency must make jurisdictional determinations on a product-by-product or brand-by-brand basis. This statement in *ASH*, however, was made in the context of a discussion of the Agency's freedom to revise its interpretation of its jurisdiction without constraint by long-standing interpretations. In *ASH*, the court found that FDA's decision to deny a citizen's petition requesting that the Agency exercise jurisdiction over cigarettes was not arbitrary, capricious, or contrary to law. *Id.* at 241, 243. The court made clear, however, that the Agency decision reviewed in the *ASH* case would not prevent FDA from revising its interpretation if new evidence became known. *Id.* at 242 n.10. New evidence would present a new "case" to the Agency that would appropriately be analyzed on its own merits.[1139] The statement in *ASH* therefore does not stand for the proposition that the Agency must make jurisdictional determinations on a manufacturer- or brand-specific basis.

[1139] *See* section IV., below, for a detailed discussion of why new evidence justifies the Agency's change in position on the application for the Act to tobacco products.

II.F.

Moreover, although it is true that the Agency often conducts product-by-product analyses of its jurisdiction under the Act, it is by no means clear that a "product" is equivalent to a "brand" or a "manufacturer" in this instance, given that different brands of cigarettes, snuff, and chewing tobacco are, respectively, virtually identical in content, size, shape, and packaging and are marketed in a closely similar manner.

Here, the Agency has elected to assert regulatory authority over cigarettes and smokeless tobacco by issuing regulations, rather than by undertaking enforcement actions against particular brands or manufacturers, and litigating, on a case-by-case basis, the status of each product. This approach is authorized by the Act. *See* section 701(a) of the Act, 21 U.S.C. 371(a) (providing "[a]uthority to promulgate regulations for the efficient enforcement of [the] Act"); *see also Hynson*, 412 U.S. at 624-625 (noting that, although regulatory agencies "usually proceed[] on a case-by-case basis, giving each [party] subject to regulation separate hearings. . . . [t]here is not always a constitutional reason why that must be done"). The Agency concludes that the approach it has adopted here has provided the manufacturers with ample opportunity to raise the numerous issues and concerns they share, as reflected in the voluminous consolidated comments submitted by both the cigarette and smokeless tobacco industries, as well as to raise evidentiary and other issues specific to individual manufacturers. The Agency further concludes that this approach is the one that most effectively serves the public health concerns the final rule seeks to address.

In support of the argument that the Agency is required to have evidence specific to each manufacturer, the comments cite cases that involved instances in which the evidence of intended use consisted *only* of labeling and promotional materials containing express

claims. These cases support the principle that a connection must exist between a manufacturer's product and the representations in labeling and promotional materials for such evidence to support a finding that the product is "intended" to be a drug or a device, for example, evidence that consumers rely on these representations. *See, e.g., United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500-501 (8th Cir. 1995); *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219, 1226-1229 (D. Minn. 1991); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 2-3 (D.D.C. 1989). *Estee Lauder*, for instance, involved traditional skin cream ingredients that by themselves were "cosmetics" but not "drugs" within the meaning of the Act. 727 F. Supp. at 3. The *only* evidence that made the products "drugs" was the manufacturer's anti-aging claims in the labeling. *Id.* In such a case, there would not be a basis to attribute Estee Lauder's drug claims to another manufacturer's skin cream whose labeling contained no drug claims. Evidence regarding drug claims in the labeling of a specific product is generally appropriately limited to the manufacturer that created or adopted the labeling and the product that accompanies the labeling.

These cases do not, however, support the argument that the Agency is required to have manufacturer-specific evidence when evidence other than labeling and promotional materials is used to determine intended use.[1140] As a result, the cases are not controlling here because the evidence of the intended use of tobacco products is not based on express

[1140] One comment also cites *Hanson v. United States*, 417 F. Supp. 30 (D. Minn. 1976), *aff'd per curium*, 540 F.2d 947 (8th Cir. 1976). In *Hanson*, the court explained that "the 'intended use' of a product . . . is determined from its label, accompanying labeling, promotional claims, advertising, *and any other relevant source*." *Id.* at 35 (emphasis added). The comment omitted the italicized language. Not only does the case not support the proposition for which it is cited, but the question of whether "intended use" determinations must be made on a product-by-product basis was not before the court.